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10/567,064	08/23/2006	Niza Frenkel	27225U	9516

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EXAMINER	
MONTANARI, DAVID A	
ART UNIT	PAPER NUMBER
1632	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,064	FRENKEL, NIZA	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-105* is/are pending in the application.

4a) Of the above claim(s) *89-105* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/13/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I claims 72-88 in the reply filed on 8/3/2009 is acknowledged. The traversal is on the ground(s) that the election/restriction requirement omits an appropriate explanation as to the existence of a serious burden if restriction was not required. Applicants continue that claim 94 was not placed into any group and should be placed into Group VII. This is not found persuasive because all of the inventions identified in Groups I-VII lack a special technical feature that is a contribution over the prior art, which is that they all relate to a DNA sequence derived from HHV-6 or HHV-7. However, Megaw et al. taught prior to the filing of the claimed invention, vectors comprising the DNA sequence encoding HHV-6. Restriction under 35 U.S.C. 121 and 372 in view of PCT Rule 13.1 and 13.2 is done with respect to a special technical feature, not the establishment of a search burden. Further the Examiner agrees that claim 94 should be grouped into Group VII and apologizes for this oversight.

The requirement is still deemed proper and is therefore made FINAL.

Claims 89-105 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/3/2009.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 72, 73, 78 and 81 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,503,752 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claimed invention and the patented invention are drawn to the DNA sequence of HHV-6 or HHV-7, vectors comprising said sequences, and the expression of foreign genes from said vectors. While patented claim 1 is drawn to a vector comprising a DNA sequence encoding HHV-6 or HHV-7, the DNA sequence derived from HHV-6 or HHV-7 in instant claim 72 would be encompassed by the sequence encoding HHV-6 or 7 in claim 1. Patented claim 4 recites that the vector will not be capable of self replication which is also claimed in instant claim 73. Patented claim 1 teaches that the recombinant DNA molecule which the vector of claim 2 comprises, will also comprise a foreign DNA sequence as recited in instant claim 78. Patented claim 1 teaches that the foreign gene can encode a protein which inhibits the proliferation of malignant cells, instant claim 81 recites that the foreign nucleic acid sequence

can encode a cytokine, of which it obvious that some cytokines are known to inhibit proliferation of malignant cells.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 72, 73 and 76-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

When the claims are analyzed in light of the specification, the instant invention encompasses any DNA sequence derived from HHV-6 or HHV-7. With respect to the description of any sequence derived from HHV-6 or HHV-7 in the construction of such a vector, the specification has only described amplicon-6 and Tamplicon-7 with respect to sequences derived from HHV-6 and HHV-7 respectively. The specification has taught the construction of vectors comprising amplicon-6 (pg. 42, Example 1) and Tamplicon-7 (pg. 43, Example 2) as well as their transfection and production of protein in J-JHAN human T cells (pg. 44, Example 3). However, the specification has failed to teach the possession of a vector comprising any DNA

sequence derived from HHV-6 or HHV-7, wherein the vector produces at least one nucleic acid sequence product in a lymphocyte cell host.

In view of these teachings, the specification has failed to teach possession of any DNA sequence derived from HHV-6 or HHV-7, other than amplicon-6 or Tamplicon-7. The claims encompass any nucleic acid fragment derived from HHV-6 or HHV-7, including a polynucleotide comprising just two or three nucleic acids derived from HHV-6 or HHV-7, wherein a product would be produced from these two or three derived nucleic acids. The specification provides no description of any derived sequences other than amplicon-6 or Tamplicon-7 that would indicate possession at the time of filing. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, only one derived sequence is described for either HHV-6 or HHV-7. The specification does not provide any disclosure as to what the complete structure would be of any DNA sequence derived from HHV-6 or HHV-7. The specification teaches no structural analysis of amplicon-6 or Tamplicon-7 that would indicate possession for other derived DNA sequences from HHV-6 or HHV-7. The skilled artisan cannot readily envision other amplicons or Tamplicons other than amplicon-6 or Tamplicon-7 taught in the specification. The specification teaches that the HHV-6A, HHV-6B and HH-V-7 genomes are linear, double-stranded DNA molecules of 162-170Kb. The genomes are composed of a 143Kb segment of unique (U) sequences, bracketed by direct repeats DRL (left) and DRR (right) (pg. 4 lines 27-30). The specification continues to teach that the most efficient cleavage occurs when the DNA molecules reach approximately full length 135-150 Kb genomes, made of identical amplicon repeats. The packaged amplicons are

replication defective, but can enter into new cells and express their transgenes at high efficiency, due to sequence reiteration." (pg. 5 lines 15-18).The specification continues to teach that the amplicon-6 vectors are expressed most efficiently in T cells, B cells, dentritic cells (pg. 26 lines 18-19). Based upon these teachings in the specification the skilled artisan cannot use just any sequence derived from HHV-6 or HHV-7 since very large unique sequences are required by the claimed vector and method. Amplicon-6 and Tamplicon-7 each describe the unique structural features and sequences that would be necessary describe the claimed invention. However, their description does not guide or teach the skilled artisan how to identify or construct any other sequences other than amplicon-6 or Tamplicon-7 and further no other sequences are taught or described that would equate to the function of inducing expression of at least one nucleic acid sequence product in a lymphocyte cell host.

In summary, the claimed invention requires very large but also unique sequences, that comprise several structural elements that are unique to HHV-6 or HHV-7. The specification has only demonstrated possession of amplicon-6 or Tamplicon-7 with no other structural analysis that would demonstrate possession of any other sequences derived from HHV-6 or HHV-7.

In conclusion, this limited information is not deemed sufficient to reasonably convey to one skilled in the art that applicant is in possession of any DNA sequence derived from HHV-6 or HHV-7 other than amplicon-6 or Tamplicon-7.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 72-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 72 is unclear. In line 7 it is stated that the "vector is adapted to induce an immune response" in a mammal. However it is not clear how a vector is adapted to induce an immune response. The specification makes no mention of adapting an immune response using the claimed vector and further the term "adapted" is present only in the claims.

Claim 88 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: expression of the gene encoded by the DNA sequence derived from HHV-6 or HHV-7 between steps (b) and (c).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 72-88 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,503,752 B1 (issued 1/7/2003).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claims 72 and 75 the '752 patent teaches that the vector can comprise Tamplicon-7, which is a DNA sequence derived from HHV-7 (col. 5 lines 20-28) and that said vector comprises an origin of replication, cleavage and packaging signal and promoter, this is taught col. 4 lines 8-16.

Regarding claim 73 the '752 patent teaches that the claimed vector will form concatemers (col. 10 lines 22-26).

Regarding claim 74 the '752 patent teaches a "vector comprising a recombinant DNA molecule having: (i) a DNA sequence derived from HHV-6 or HHV-7 and comprising an origin of DNA replication, a promoter sequence capable of inducing expression in a lymphatic host cell of a downstream nucleic acid sequence and a cleavage and packaging signal; (ii) a foreign nucleic acid sequence downstream to an expression control of said promoter sequence" (col. lines 8-17).

Regarding claim 76 the '752 patent teaches that the vector is packaged in a virion particle (col. 10 lines 45-63).

Regarding claim 77 the '752 patent teaches that HHV-6 expression leads to exanthem subitum, which is an immune response to HHV-6 protein expression.

Regarding claims 78 and 81 the '752 patent teaches that the vector of the claimed invention can comprise a foreign nucleic acid sequence such as a detectable marker (col. 8 lines 65-58 bridge col. 9 lines 1-4).

Regarding claims 79 and 80 the '752 patent teaches that the foreign nucleic acid sequence can be targeted to the cell membrane (col. 7 lines 46-59) or secreted out of the cell (col. 7 lines 60-67) where the production of insulin or enzymes are used to treat diseases associated with their deficincies.

Regarding claim 82 the '752 patent teaches that their claimed vector is "useful as an agent for genetic therapy in the treatment of various malignancies, viral infections, enzyme deficiencies and others, of lymphatic cells as well as other cells capable of being infected with HHV-6 or HHV-7" (col. 5 lines 18-22).

Regarding claims 83 and 84 the '752 patent teaches that a helper virus will be provided along with the claim vector to assist in the replication of the Tamplicon (col. 5 lines 26-29) and that a cell will comprise the helper virus (col. 12 lines 42-49).

Regarding claims 85, 86 and 87 the '752 patent teaches that the vector of the invention may also be used for infection of lymphocytes ex vivo and then returned to a patient (col. 7 lines 29-41 and col. 8 lines 49-53), wherein the vector comprises a foreign nucleic acid sequence (col. 8 lines 65-58 bridge col. 9 lines 1-4). Further it is art accepted that lymphocytes comprise B and

T cells and thus the lymphocytes infected by the vector taught in '752 would encompass the B and T cells of claim 87.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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